REMARKS

In view of the following remarks, the Examiner is requested to reconsider and allow Claims 1 -34, the only claims pending and under examination in this application.

Claim 32 has been amended to specify that the percentage is in terms of w/w, as supported by the specification at page 6, lines 2 to 7. Claim 34 has been added and finds support in the claims and specification as originally filed. As the above amendment sintroduce no new matter to the application, their entry by the Examiner is respectfully requested.

CLAIM REJECTION – 35 U.S.C. §112, 2ND ¶

Claim 32 has been rejected under 35 U.S.C. §112, second paragraph. In view of the above amendment to Claim 32, this rejection may be withdrawn.

CLAIM REJECTIONS – 35 U.S.C. §103

Claims 1 – 18 and 24 – 28 as well as 29-33 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921).

In maintaining this rejection, the Examiner has found the recently filed Declaration by Dr. Bradley Galer non-persuasive because:

> persuasive. The examiner has considered the affidavit submitted under 37 C.F.R. 1.132, but it is not considered to be persuasive. Although the examiner appreciates the applicant's efforts to shed light on this issue, the affidavit does not negate the plain disclosure of the prior art, because the submitted affidavit still does not establish the term "musculoskeletal disorder" and "entrapment neuropathy" as being entirely mutually exclusive terms as far as they both relate to carpal tunnel syndrome. Therefore, the examiner cannot find the instantly claimed invention to be allowable at this time.

As such, the Examiner still believes, despite the recently filed declaration, that Petrus actually refers to carpal tunnel syndrome as a type of musculoskeletal disorder.

However, contrary to the Examiner's understanding, the only mention of Carpal Tunnel Syndrome in Petrus appears in the background section of this patent. Furthermore, the mention of Carpal Tunnel Syndrome is not in the context of Carpal Tunnel Syndrome being an example of a musculoskeletal disorder. The relevant section of Petrus reads as follows:

> Occupational injuries however, have become this country's most costly form of illnesses. The Bureau of Labor Statistics reported in 1992, that one half of the 2.3 million nonfatal occupational injuries and illnesses which resulted in days away from work involved musculoskeletal disorders. The Occupational Safety and Health Administration (OSHA) estimates in 1999, that more than 647,000 Americans suffer from injuries or illnesses due to work-related musculoskeletal disorders (WMSDs). These disorders account for more than 34% of all workdays lost to injuries and illnesses and cost employers $15 to $20 billion per year in direct workers' compensation costs and another $100 billion on lost productivity, employee turnover, and other indirect expenses. Cumulative trauma disorders (CTDs) frequently involve the upper extremities, such as wrists, shoulders or elbows. Carpal tunnel syndrome of the wrist has become the fastest growing occupational hazard in the United States today.

In the above discussion, Petrus refers to Carpal Tunnel Syndrome as a type of occupational hazard, but not as a musculoskeletal disorder. Furthermore, the very next line of the Petrus specification reads:

> Arthritis, a musculoskeletal disorder, is the leading cause of disability in the United States. The Centers for Disease

As such, if Petrus actually viewed Carpal Tunnel Syndrome as a type of muscoloskeletal disorder, Petrus would have clearly referred to it as such.

The previously submitted declaration by Dr. Bradley Galer clearly demonstrates that one of skill in the art would read Petrus' disclosure as limited to the treatment of musculoskeletal disorders and that one of skill in the art would not consider Carpal Tunnel Syndrome to be a musculoskeletal disorder.

As pointed out above, nothing in Petrus negates Dr. Galer's statements and the Examiner has not provided any other evidence sufficient to negate Dr. Galer's statements.

In view of the lack of such evidence, the Examiner must accept the statements of Dr. Galer in the previously filed declaration and accept that Petrus is deficient in failing to either teach or suggest anything about treating a condition such as Carpal Tunnel Syndrome.

Additionally, the combined teaching of Petrus, Edwards and Biedermann fails to provide a reasonable expectation of success in the Applicants' invention. As explained in the Declaration of Dr. Larry Caldwell filed in conjunction with the Applicants' April 26, 2004 response, a reasonable expectation of success cannot be expected by modifying the invention of Petrus in view of Edwards and Biedermann, for the reasons provided in the declaration.

These reasons included the following:

> (a) it is well known in the art that just because an active agent is administered orally to treat a medical condition does not mean that it can be effective when administered topically to treat the same or different medical condition; and
>
> (b) it is well known in the art that just because an active agent is administered topically to treat one condition does not mean that it can be effective when topically administered to treat other conditions.

In asserting that the Caldwell declaration was not persuasive, the Examiner appeared to view these statements as unsubstantiated opinion which could not be accorded any weight.

However, according to the MPEP §716.01 (c):

"Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue."

Dr. Caldwell is a reasonably skilled practitioner in the field. His declaration is not submitted as to the ultimate legal conclusion at issue, i.e., obviousness. Rather it is submitted to establish what a reasonably skilled practitioner in the art knows.

In addition, the Applicants submit herewith a supplemental declaration by Dr. Bradley Galer which agrees with the statements made by Dr. Larry Caldwell in the previously filed declaration and supports the above excerpted opinions with publications that support these opinions.

In view of the record of the present application, the Applicants have clearly demonstrated that:

- Petrus in combination with Edwards and Biedermann fails to teach or suggest any treatment for non-musculoskeletal disorders, such as Carpal Tunnel Syndrome; and
- The combined teaching of the references fails to provide one of skill in the art with a reasonable expectation of the success the claimed methods.

Because the combined teaching of the cited references fails to teach or suggest all of the elements of the claimed invention and fails to provide one of skill in the art with a reasonable expectation of success in the claimed methods, as reviewed above,

Claims 1 – 18 and 24 -33 are not obvious under 35 U.S.C. §103(a) over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921) and this rejection may be withdrawn.

Claims 19-23 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Petrus (USPN 6,399,093) in view of Edwards (USPN 5,989,559) and Biedermann, et al. (USPN 5,980,921) and further in view of Shudo. As demonstrated above, Petrus, Edwards and Biedermann do not teach or suggests every limitation of or provide a reasonable expectation of success in the claimed invention. As Shudo was cited for its disclosure of kits containing topical patch formulations and instructions, it fails to remedy the defects of Petrus, Edwards and Biedermann, and therefore a prima facie case of obviousness has not been established with respect to Claims 19 – 23. Accordingly, the Applicants respectfully request the Examiner reconsider and withdraw this rejection.

New Claim 34 is patentable for at least the reasons provided above.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CALD-005.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: November 21, 2006

By: _____
Bret E. Field
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enc:

- Declarations by Dr. Bradley Galer

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